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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,501	07/30/2001	Hans-Peter Krimmer	210740US0X	1206

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/27/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,501

Applicant(s)

KRIMMER ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/26/01 & 9/23/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The STIC has corrected the CRF by deleting "<160> 6" at the end of line <151> and placing the "6" at the end of line "<161>". Applicants should take note of this if they file a continuation of the application.

Applicant's election with traverse of Group I, claims 1-10 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the restriction requirement is unsustainable and that it would not be a burden upon the examiner to examine all of the claims. After further consideration, it is agreed to examine all of the claims, 1-11.

The disclosure is objected to because of the following informalities:

On page 6, lines 14-15 are unclear in the recitation of "[that are available separately, which]". What is meant by this?

Appropriate correction is required.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 are indefinite in the recitation of "the reactions". There is no antecedent basis for this term in claim 1.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or

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use the invention. This is a combination written description and enablement rejection.

The specification teaches on page 7 that when a DL-allysine hydantoin is mixed with *E. coli* cells and left for 4 hours at 37°C, a yield of L-allysine acetal of >85% was obtained having an optical purity of >99%. There is nothing else taught in the specification that would reasonably convey to one skilled in the art that the claimed invention of the instant claims was in the possession of applicants when the application was filed. The specification also does not teach one of ordinary skill in the art how to make the claimed invention. The claims are drawn to contacting a hydantoin of a very general formula with a hydantoinase and a D- or L-specific carbamoylase "under conditions suitable for *in situ* racemisation [sic, racemization] of the hydantoin or of an N-carbamoyl amino acid". The specification does not teach that a hydantoin was ever contacted with the two enzymes of claim 1 but rather with whole *E. coli* cells. It also does not teach what "conditions suitable for *in situ* racemisation" are. It is not understood what is meant by the second part of this phrase "or of an N-carbamoyl amino acid". Furthermore it does not teach that any of the requirements of the claims 2-11 were ever performed or what the effect would be if they were. The specification does not teach one how to produce "a pharmaceutical or biologically active product using an acetal produced by the process of claim 1". What pharmaceutical is to be produced? What biologically active product is to be produced? How is the acetal produced by claim 1 to be used to produce these substances?

The specification also does not teach one how to make (perform) the claimed method as it does not teach the use of the specific enzymes of claim 1, how to obtain them, in what amounts to use each one, under what conditions

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to perform the method, etc. The specification does not even characterize what "E. coli JM109" is. If this is in one of the references specifically incorporated by reference it is deemed to be essential matter and should be incorporated in the instant specification alone with proof that it was in the specifically incorporated reference. Applicants are reminded that essential matter may be incorporated only from U.S. Patents, U.S. Patent Publications or U.S. Patent applications (MPEP 608.01(p)(I)(A)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Pietzsch, et al. (U) or Sylatk, et al. (V). Pietzsch, et al. teach that hydantoinase and L-N-carbamoylase can produce "natural and unnatural, optically pure L-amino acids starting with D,L-5-monosubstituted hydantoins" (see at least the abstract). Sylatk, et al. teach on page 323 that D,L-5-monosubstituted hydantoins can be converted by a hydantoinase and a carbamoylase to D- or L-amino acids, with the formulae on page 323 meeting the requirements of the instant claims. They further teach that "most of the 5-monosubstituted hydantoins are racemizing already under reaction conditions when the enzyme are still active...[and that] it is possible to convert the racemic substrates totally to the optically pure D- or L-amino acids without any chemical reaction step necessary.

Claim 1 is drawn to a process for making allysine acetal from a hydantoin by using a hydantoinase and a carbamoylase. It is maintained that the


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main part of the claim is taught by the two instant references. Apparently the conversion of the hydantoin to the amino acid derivative with the loss of a NH_3 and a CO_2 is the reaction of interest and what side chains are added on to these substances are incidental, absent convincing proof to the contrary. The instant references teach claim 1 in that the "R" in Syldatk, et al. and the use of the term "natural and unnatural, optically pure L-amino acids" in Pietzsch, et al. meet the requirement of producing allysine. The other claims would have been obvious to one of ordinary skill in the art given the general state of knowledge in the art, absent unexpected results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
November 22, 2002